

| | | |
|--|---------------------|-------------------|
| SUBSTITUTE FORM PTO-1449 (MODIFIED) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b)) | Attorney Docket No. | 50304/014002 |
| | Serial No. | 10/595,293 |
| | Applicant | VERBRUGGEN et al. |
| | Filing Date | April 5, 2006 |
| | Group | 1635 |
| | IDS Filed | November 13, 2007 |
| | Customer No. | 21559 |

| | | | |
|-----------------------|--|--|--|
| U.S. PATENT DOCUMENTS | | | |
|-----------------------|--|--|--|

| Examiner's Initials | Document Number | Publication Date | Patentee or Applicant |
|---------------------|-----------------|------------------|-----------------------|
| | | | |

| | | | | |
|--|--|--|--|--|
| FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION | | | | |
|--|--|--|--|--|

| Examiner's Initials | Document Number | Publication Date | Country or Patent Office | Translation (Yes/No) |
|---------------------|-----------------|------------------|--------------------------|----------------------|
| | | | | |

| | |
|---|--|
| OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION) | |
|---|--|

| | |
|--|--|
| | Bresnihan et al., "Treatment of Rheumatoid Arthritis with Recombinant Human Interleukin-1 Receptor Antagonist." Arthritis Rheum. 41:2196-2204 (1998) |
| | Bresnihan & Cobby, "Clinical and Radiological Effects of Anakinra in Patients with Rheumatoid Arthritis." Rheumatology 42:Suppl 2, ii22-ii28. (2003) |
| | Giannoukakis et al. "Adenoviral Gene Transfer of the Interleukin-1 Receptor Antagonist Protein to Human Islets Prevents IL-1beta-Induced Beta-Cell Impairment and Activation of Islet Cell Apoptosis In Vitro." Diabetes 48:1730-1736 (1998) |
| | Jacobs et al., "Experimental Autoimmune Encephalomyelitis is Exacerbated by IL-1Alpha and Suppressed by Soluble IL-1 Receptor." J. Immunol. 146:2983-2989 (1991) |
| | Jiang et al., "A Multicenter, Double-Blind, Dose-Ranging, Randomized, Placebo-Controlled Study of Recombinant Human Interleukin-1 Receptor Antagonist In Patients with Rheumatoid Arthritis: Radiologic Progression and Correlation of Genant and Larsen scores." Arthritis Rheum. 43:1001-1009 (2000) |
| | Lim et al., "Local Expression of Interleukin-1 Receptor Antagonist by Plasmid DNA Improves Mortality and Decreases Myocardial Inflammation in Experimental Coxsackieviral Myocarditis." Circulation 105:1278-1281 (2002) |
| | Maedler et al. "Glucose-Induced Beta-Cell Production of IL-1Beta Contributes to Glucotoxicity in Human Pancreatic Islets" J. Clin. Invest. 110:851-860 (2002) |
| | Martin & Near, "Protective Effect of the Interleukin-1 Receptor Antagonist (IL-1ra) on Experimental Allergic Encephalomyelitis in Rats." J. Neuroimmunol. 61:241-245 (1995) |
| | Moore et al., "The Inflammatory Milieu Associated with Conjunctivalized Cornea and Its Alteration with IL-1 RA |

| | |
|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant. | |

| | | | |
|--|--|---------------------|-------------------|
| SUBSTITUTE FORM PTO-1449 (MODIFIED) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. § 1.98(b)) | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | Attorney Docket No. | 50304/014002 |
| | | Serial No. | 10/595,293 |
| | | Applicant | VERBRUGGEN et al. |
| | | Filing Date | April 5, 2006 |
| | | Group | 1635 |
| | | IDS Filed | November 13, 2007 |
| Customer No. | 21559 | | |

| U.S. PATENT DOCUMENTS | |
|-----------------------|---|
| | Gene Therapy." Invest. Ophthalmol. Vis. Sci. 43:2905-2915 (2002) |
| | Rudinskaya & Trock, "Successful Treatment of a Patient with Refractory Adult-Onset Still Disease with Anakinra." Clin. Rheumatol. 9:330-332 (2003) |
| | Yang et al., "Attenuation of Ischemic Inflammatory Response in Mouse Brain Using an Adenoviral Vector to Induce Overexpression of Interleukin-1 Receptor Antagonist." J. Cereb. Blood. Flow. Metab. 18:840-847 (1998) |
| | Yokoo et al., "Genetically Modified Bone Marrow Continuously Supplies Anti-Inflammatory Cells and Suppresses Renal Injury in Mouse Goodpasture Syndrome." Blood 98:5764 (2001) |

| | |
|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant. | |